

1634

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



In re Application of : Thomas C. Hart  
Serial No. : 10/031,889  
Filing Date : 01/25/2002  
Examiner : Myers, Carla J.  
Group Art Unit : 1634  
Entitled : METHODS AND COMPOSITIONS  
FOR DIAGNOSING PALMOPLANTAR  
KERATODERMAS AND DYSPLASIAS  
AND OTHER PERIODONTAL  
DISEASES

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*Janice M. Nightlinger*  
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Alexandria, VA 22313-1450

**TRAVERSAL AND REQUEST FOR****RECONSIDERATION OF REQUIREMENT FOR RESTRICTION**

Dear Sir:

Applicants, through their undersigned agents, hereby  
traverse and request reconsideration of the requirement for  
restriction set forth in the Official Action dated September  
15, 2003 in the above-identified patent application. A

shortened statutory response period of one (1) month was set in the September 15, 2003 Official Action. This traversal and Request for Reconsideration of Requirement for Restriction is being filed within the aforementioned response period.

It is noted that the Examiner regards the present Application as allegedly containing groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1. These groups are:

- Group I, claims 1-10 and 13-38, drawn to nucleic acids and methods of detecting nucleic acids;
- Group II, claim 11, drawn to proteins; and
- Group III, claims 12, 39, and 40, drawn to antibodies.

Applicants respectfully submit that the above assertion by the Examiner is improper for failing to comply with the relevant provisions of the Manual of patent Examining Procedure (M.P.E.P.) pertaining to unity of invention determination.

As stated in 1893.03(d) of the M.P.E.P.:

The principles of unity of invention are used to determine the types of claimed subject matter and the combinations of claims to different categories of invention that are permitted to be included in a single international or national stage patent application. The basic principle is that an application should relate to only one invention or, if there is more than one invention, that applicant would have a right to include in a single application only those inventions which are so linked as to form a single general inventive concept.

A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution

which each claimed invention, considered as a whole, makes over the prior art. ... Note also examples 1-17 of Annex B Part 2 of the PCT Administrative Instructions as amended July 1, 1992 contained in Appendix AI of the MPEP.

In the instant case, claims 1-10 and 13-38 of Group I are directed to nucleic acid molecules encoding altered CTSC proteins and their uses; claim 11 of Group II are directed to altered CTSC proteins encoded by the nucleic acids encompassed by the claims in Group I; and claims 12, 39, and 40 of Group III are directed to antibodies immunologically specific for the altered CTSC proteins encoded by the nucleic acids encompassed by the claims in Group I. Therefore, all pending claims, claims 1-40, share a special technical feature, i.e. altered CTSC proteins. Inasmuch as the altered CTSC proteins of the present invention are unique and novel, the inventions of Groups I-III should be considered as being linked to a single invention concept and the claims of Groups I-III should be examined together.

Further, it is stated in the Example 17 of Annex B Part 2 of PCT Administrative Instructions:

... Example 17

Claim 1: Protein X.

Claim 2: DNA sequence encoding protein X.

Expression of the DNA sequence in a host results in the production of a protein which is determined by the DNA sequence. The protein and the DNA sequence exhibit corresponding special technical features. Unity between claims 1 and 2 is acceptable.

Thus, a protein and the DNA sequence encoding it exhibit "corresponding special technical features" and, therefore, satisfy the PCT's unity of invention requirement. In the instant case, claim 11 of Group II is directed to altered CTCS proteins encoded by the nucleic acids encompassed by the

claims of Group I. Therefore, at the very least, the claims of Groups I and II should be examined together.

Additionally, it is noted that the Examiner has further requested that a single mutation selected from the group of mutations set forth in Table 1 be elected. This further requirement to elect a single mutation is also traversed.

Specifically, the Examiner cites PCT Rule 13.2 and the guidelines in Section (f)(i)(A) of Annex B of the PCT Administrative Instructions and asserts that the chemical compounds are not regarded as being of a similar nature because all of the alternatives do not share a common property or activity. This assertion is erroneous because each of the mutations listed in Table 1 is associated with an aberrant CTSC protein, the presence of which results in palmoplantar ectodermal disorders/dysplasias and periodontal diseases. The claimed DNA molecules and proteins encoded thereby also share a common property and activity. Moreover, as it is stated in Section (f) of Annex B of the PCT Administrative Instructions:

(f) **"Markush Practice."** The situation involving the so-called "Markush practice" wherein a single claim defines alternatives (chemical or non-chemical) is also governed by Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

Thus, contrary to the Examiner's assertion, the altered CTSC proteins and their coding sequences listed in Table 1 do share special technical feature, i.e. these altered CTSC proteins are all related to palmoplantar ectodermal disorders/dysplasias and periodontal diseases. Accordingly, a requirement to elect a single mutation listed in Table 1 is improper. Further, it is noted that the following mutations in Table 1 are related to Papillon-Lefevre syndrome (PLS):

199-222del  
445-446insATGT  
458C→T  
622-623insC  
704G→A  
748C→T  
815G→C  
856C→T  
898G→A  
901G→T  
901G→A  
910T→A  
956A→G  
1015C→T  
1019A→G  
1028-1029delCT  
1047delA  
1286G→A, and  
1360A→G

Therefore, the mutations which cause PLS, as set forth above, should, at the very least, be examined together.

Additionally, it is worth mentioning that this application is a §371 filing of PCT/US00/20400 and that during the examination of the PCT application, the claims were found to have unity of invention. Accordingly, this restriction requirement is improper for not complying with the unity of invention finding before the PCT Office.

In light of the foregoing, Applicants respectfully traverse the restriction requirement of September 15, 2003 and request that it be withdrawn, or at the very least modified, upon reconsideration.


In order to be fully responsive to the above-mentioned requirement, Applicants hereby elect the subject matter of Group I, i.e., claims 1-10 and 13-38 for examination in this application. Applicants further elect the mutation listed in Table 1 as "1286G→A" in exon 7 be examined in this application. Should the Examiner agrees with Applicants' remarks regarding the reconsideration of the further restriction requirement to elect one mutation, Applicants would like to elect the mutations related PLS for further examination in this application.

Applicants' election in response to the present restriction requirement is without prejudice to their right to file one or more continuing applications, as provided in 35 U.S.C. §121, on the subject matter of any claims finally held withdrawn from consideration in this application.

Early and favorable action on the merits of this application is respectfully requested.

Respectfully submitted,  
DANN DORFMAN HERRELL and  
SKILLMAN, P.C.  
Agent for Applicants

By

  
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